IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Docket No. 17-72260
Consolidated with Docket Nos. 17-72501, 17-72968,
17-73290, 17-73383, 17-73390

SAFER CHEMICALS, HEALTHY FAMILIES et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY et al.,

Respondents.

IPC INTERNATIONAL, INC. et al.,

Respondents-Intervenors.

On Petition for Review of Final Rules of the U.S. Environmental Protection Agency

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OPENING BRIEF OF PETITIONERS:

ALASKA COMMUNITY ACTION ON TOXICS; ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS; ASBESTOS DISEASE AWARENESS ORGANIZATION; CAPE FEAR RIVER WATCH; ENVIRONMENTAL DEFENSE FUND; ENVIRONMENTAL HEALTH STRATEGY CENTER; ENVIRONMENTAL WORKING GROUP; LEARNING DISABILITIES ASSOCIATION OF AMERICA; NATURAL RESOURCES DEFENSE COUNCIL; SAFER CHEMICALS, HEALTHY FAMILIES; SIERRA CLUB; UNION OF CONCERNED SCIENTISTS; UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO/CLC; VERMONT PUBLIC INTEREST RESEARCH GROUP; and WE ACT FOR ENVIRONMENTAL JUSTICE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners Safer Chemicals, Healthy Families; Asbestos Disease Awareness Organization; Vermont Public Interest Research Group; Environmental Defense Fund; Alliance of Nurses for Healthy Environments; Cape Fear River Watch; Natural Resources Defense Council; Alaska Community Action on Toxics; Environmental Health Strategy Center; Environmental Working Group; Learning Disabilities Association of America; Sierra Club; Union of Concerned Scientists; WE ACT for Environmental Justice; and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC submit that they have no parent corporations and no publicly issued stock shares or securities. No publicly held corporation holds stock in any of the petitioners.

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PRELIMINARY STATEMENT

Toxic chemicals pervade our environment. Chemicals pollute our air, soil, and water, and contaminate our homes, workplaces, and consumer products.

Congress enacted the Toxic Substances Control Act (TSCA) in 1976 to give the U.S. Environmental Protection Agency (EPA or Agency) authority to "look comprehensively at the hazards associated with [a] chemical" and to prevent harm to health and the environment through regulation of chemicals posing unreasonable risks. S. Rep. No. 94-698, at 2 (1976). Nonetheless, the vast majority of chemicals in commerce have never been reviewed by EPA for safety and remain unregulated. This near-total failure to address chemical risks led Congress to amend TSCA in 2016, establishing a mandatory process to systematically evaluate and manage the risks of existing chemicals.

To implement this new mandate, Congress required EPA to issue two rules, known as the Framework Rules, establishing the processes by which EPA will prioritize chemicals for risk evaluations and then conduct those evaluations. The evaluation results—a finding of whether a chemical presents an unreasonable risk to health or the environment—dictate whether the Agency must ban, restrict, or otherwise regulate the chemical to prevent the risk.

Risk—the likelihood of harmful effects to human health or ecological systems—is determined by the toxicity of a chemical (i.e., its hazard) combined

with how much contact (i.e., exposure) a person or ecological receptor has with the chemical.[1] Often, individuals are exposed to a chemical from multiple uses and through a variety of exposure pathways. Thus, TSCA can effectively protect against chemical harm only if EPA evaluates *all hazards and all exposures.* If EPA does not fully consider all known and reasonably foreseen hazards and exposures during a risk evaluation, the evaluation cannot accurately characterize the true risk posed by the chemical. Accordingly, the law requires EPA to examine broadly all of a chemical's "conditions of use," a term TSCA defines to encompass a chemical's entire lifecycle, starting with manufacture and processing, and continuing through distribution, use, and disposal.

EPA proposed the Framework Rules in January 2017 to implement Congress's mandate. The proposals complied with TSCA's requirement to comprehensively evaluate a chemical's hazards and exposures and make a holistic determination of whether the chemical presents an unreasonable risk of injury.

In the spring of 2017, a former chemical-industry advocate who had just been appointed by the new administration oversaw the final drafting of the Framework Rules. Following this appointment, EPA abruptly reversed course and adopted the approach favored by the chemical industry, in many instances revising

[1] U.S. EPA, *About Risk Assessment*, https://www.epa.gov/risk/about-risk-assessment.

the rules to match the chemical industry's comments word for word. In the final Framework Rules, EPA asserts unfettered discretion to exclude known or reasonably foreseen exposure pathways from consideration, thereby ignoring important contributors to a chemical's overall risk.

The Framework Rules unlawfully narrow the scope of risk evaluations by allowing EPA to exonerate chemicals based on only a partial review of known or reasonably foreseen uses and exposures. The Rules thereby threaten to leave the public—and especially vulnerable groups like children, pregnant women, and workers—inadequately protected from the potential risks of the thousands of chemicals to which individuals are exposed every day. Essential parts of the Rules violate Congress's unambiguous command to evaluate each chemical holistically and comprehensively, and those parts must be set aside.

STATEMENT OF JURISDICTION

Respondents EPA and Administrator Scott Pruitt (together, EPA) issued the Framework Rules pursuant to their authority under TSCA. 15 U.S.C. § 2605(b)(1)(A), (b)(4)(B); ER 1, 29.[2] The U.S. Courts of Appeals have jurisdiction to review the final Rules. 15 U.S.C. § 2618(a)(1)(B). Venue is proper in this Court because Petitioner Alaska Community Action on Toxics resides in

[2] Petitioners use "ER" to refer to the Excerpts of Record and "PA" to refer to Petitioners' Addendum of Declarations in Support of Standing.

Alaska, and Petitioners Asbestos Disease Awareness Organization and Sierra Club reside in California. PA 5, 51, 321.

The Framework Rules were published on July 20, 2017, ER 1, 29, and issued for purposes of judicial review on August 3, 2017, *see* 40 C.F.R. § 23.5. Petitioners filed timely petitions for review in three Courts of Appeals on August 10 and 11, 2017. *See* 15 U.S.C. § 2618(a)(1)(A); Pet'rs' Joint Opp'n to Resps.' Mot. to Transfer 4-5, ECF No. 18 (listing petitions). All six petitions challenging the Rules were subsequently consolidated in this Court. Order, No. 17-1926 (4th Cir. Dec. 11, 2017), ECF No. 63; Order, No. 17-72260 (9th Cir. Jan. 3, 2018), ECF No. 34; *see* 28 U.S.C. § 2112(a)(3), (a)(5).

STATEMENT OF ISSUES PRESENTED

1. Congress directed EPA to conduct risk evaluations to determine whether "a chemical substance" presents an unreasonable risk of injury to health or the environment under "the conditions of use." 15 U.S.C. § 2605(b)(1)(A).

   a. Does TSCA grant EPA authority to pick and choose which conditions of use it will consider in prioritizing chemicals and conducting risk evaluations?

   b. Does TSCA permit EPA to conclude a risk evaluation without determining whether the chemical substance as a whole presents an unreasonable risk?

c. Does TSCA permit EPA to determine that individual conditions of use do not present an unreasonable risk before completing its evaluation of the chemical substance as a whole?

2. Congress defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Has EPA unlawfully rewritten this definition by excluding a chemical's ongoing and future use and disposal from "conditions of use" if the chemical's manufacture, processing, and distribution for that specific use have been discontinued?

3. Congress directed EPA to consider all "reasonably available" information when making priority designations and conducting risk evaluations. 15 U.S.C. § 2625(k). Are the Framework Rules contrary to this mandate or arbitrary and capricious because they (a) penalize incomplete submissions by public commenters; (b) create thresholds for considering scientific information; (c) allow manufacturers to withhold relevant information about a chemical when requesting risk evaluations; and/or (d) fail to require EPA to consider during prioritization whether it has adequate information to conduct a risk evaluation?

STATUTORY ADDENDUM

Petitioners attach a separate Statutory Addendum to their Opening Brief. 9th Cir. R. 28-2.7.

STATEMENT OF THE CASE

I. The Toxic Substances Control Act

A. The unfulfilled promise of the 1976 enactment

Congress enacted TSCA in 1976 to "prevent unreasonable risks of injury to health or the environment" from chemicals. S. Rep. No. 94-698, at 1; Pub. L. No. 94-469, 90 Stat. 2003 (codified at 15 U.S.C. § 2601 et seq.) (1976). Then-existing environmental laws were "clearly inadequate" to address the "serious risks of harm" to public health from toxic chemicals. H.R. Rep. No. 94-1341, at 7 (1976); *see* S. Rep. No. 94-698, at 3 ("[W]e have become literally surrounded by a man-made chemical environment. … [T]oo frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers."). While other federal environmental laws focused on specific media, such as air or water, none gave EPA authority to "look comprehensively" at the hazards of a chemical "in total." S. Rep. No. 94-698, at 2.

Congress designed TSCA to fill these "regulatory gaps," S. Rep. No. 94-698, at 1, through a comprehensive approach to chemical risk management that considered "the full extent of human or environmental exposure," H.R. Rep. No.

94-1341, at 6. However, the 1976 law proved ineffective at reducing risks to public health from toxic chemicals existing in commerce.

First, while TSCA section 6 required EPA to restrict unsafe chemicals, *see* 90 Stat. 2003, § 6(a), it did not establish a systematic process or schedule for evaluating whether chemicals present unreasonable risks of injury to health or the environment. As a result, EPA rarely restricted or banned existing chemicals, and these chemicals could remain in commerce indefinitely without any safety review by EPA. S. Rep. No. 114-67, at 4 (2015).

Second, EPA's use of section 6 was hampered by a court ruling invalidating EPA's 1989 ban on most uses of asbestos. *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The court overturned EPA's asbestos rule on the grounds that EPA's cost-benefit analysis was flawed and that EPA failed to impose the "least burdensome" risk mitigation measure among available alternatives. *Id.* at 1215-17. Following this decision, EPA's section 6 rulemaking came to a standstill: EPA has not finalized a rule regulating an existing chemical under section 6 in nearly thirty years. S. Rep. No. 114-67, at 4. In fact, in the more than forty years since TSCA's enactment, EPA has only five times used its section 6 authority to ban, limit production of, or restrict the use of existing chemicals.[3]

[3] *See* U.S. Gov't Accountability Office, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program* 18 (June 2005), https://www.gao.gov/products/GAO-05-458.

B. The 2016 amendments

In 2016, Congress overhauled TSCA by enacting the Frank R. Lautenberg Chemical Safety for the 21st Century Act (together with the 1976 law, the amended statute is referred to as TSCA). Pub. L. No. 114-182, 130 Stat. 448 (codified at 15 U.S.C. § 2601 et seq.) (2016). Congress affirmed that the intent of the original law—to give EPA "authority to look at the hazards [of chemicals] in total," S. Rep. No. 94-698, at 2—remained "intact." S. Rep. No. 114-67, at 7.

The 2016 amendments establish new requirements in section 6 for EPA to systematically evaluate the potential risks presented by existing chemicals. The Agency must now undertake a step-by-step process to (1) select, i.e., "prioritize" chemical substances needing evaluation based on their potential risk to health and the environment; (2) conduct "risk evaluations" of those prioritized chemicals, and some chemicals nominated by manufacturers, to determine whether they present unreasonable risks of injury to health or the environment; and (3) eliminate such risks by issuing rules regulating those chemicals. 15 U.S.C. § 2605(a)-(b).

Throughout the amendments to section 6, Congress used a new term, "conditions of use," to describe the circumstances EPA must consider when prioritizing chemicals for review and conducting risk evaluations. The statute broadly defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or

reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4). The amendments also clarified that EPA's "unreasonable risk" determination must be made "without consideration of costs" and removed the "least burdensome" requirement—modifying language that had doomed the asbestos ban. *Id.* § 2605(a), (b)(4)(A).

1. Prioritization

TSCA requires EPA to establish a "risk-based screening process," called prioritization, to guide EPA's selection of chemicals warranting full risk evaluation. Chemicals designated as "high-priority"—meaning they "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use," *id.* § 2605(b)(1)(B)(i)—will undergo immediate risk evaluations. *Id.* § 2605(b)(3)(A). Chemicals designated as "low-priority"—a designation that must be based on "information sufficient to establish" that the chemical "does not meet the standard" for high-priority designation, *id.* § 2605(b)(1)(B)(ii)—will not undergo further review at that time. *Id.* § 2605(b)(1)(A).

2. Risk evaluations

Once EPA designates a chemical as high-priority, it must initiate a risk evaluation for that chemical and complete it within three years (with a possible six-month extension). *Id.* § 2605(b)(3)(A), (b)(4)(G). EPA must also conduct risk

evaluations on some chemicals nominated by their manufacturer(s). *Id*. § 2605(b)(4)(C)(ii). Manufacturer-requested risk evaluations must follow the same process and meet the same requirements as EPA-initiated evaluations. *See id.* § 2605(b)(4)(C), (b)(4)(E)(ii).

> Through each risk evaluation, EPA must
>
> > determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors … under the conditions of use.

Id. § 2605(b)(4)(A). EPA must evaluate risks not only to the general population, but also to relevant "potentially exposed or susceptible subpopulation[s]." *Id.* These include groups such as "infants, children, pregnant women, workers, or the elderly," that, "due to either greater susceptibility or greater exposure," may face greater risks of harm than the general population from chemical exposures. *Id.* § 2602(12).

As an initial part of the evaluation, EPA must publish the "scope" of the evaluation, describing "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." *Id*. § 2605(b)(4)(D). EPA must also, among other requirements, "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance." *Id.* § 2605(b)(4)(F)(i). This is because characterizing exposure involves gathering information on the various

conditions of use of a chemical to determine the potential pathways of exposure to the chemical and estimate the extent of exposure to people or environmental receptors, including the duration, intensity, frequency, and number of exposures. *Id*. § 2605(b)(4)(F)(iv); *see* ER 52-54. Characterizing hazard involves reviewing scientific studies to determine the nature and severity of the harms caused by the chemical. ER 54-56. Ultimately, the risk evaluation will combine EPA's exposure and hazard assessments to estimate the risk the chemical presents. ER 56-57.

3. Risk management rules

If EPA determines "that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk" to health or the environment, EPA must issue a rule under section 6(a) to address the risk. 15 U.S.C. § 2605(a), (c)(1). This rule must impose restrictions or other requirements designed to eliminate the unreasonable risk. *Id*. § 2605(a). Such requirements may include full or partial bans on manufacture, processing, or distribution; warning labels; recordkeeping requirements; use restrictions; and prohibitions or limits on methods of disposal. *Id*.

4. Obtaining information

TSCA requires EPA to consider information relating to a chemical that is "reasonably available to the Administrator" throughout the prioritization and risk evaluation processes. *Id.* § 2625(k). To allow EPA to obtain and develop "the information necessary to fill knowledge gaps before making regulatory decisions," H.R. Rep. No. 114-176, at 23 (2015), Congress expanded EPA's information-gathering authorities as part of the 2016 amendments. *See id.* at 22-23; 15 U.S.C. § 2603(a)(1), (a)(2).

II. History of the Framework Rules

Congress required EPA to issue the Framework Rules to implement the amendments to section 6. 15 U.S.C. § 2605(b)(1)(A), (b)(4)(B).

A. The proposed Rules

EPA issued the proposed Prioritization and Risk Evaluation Rules on January 17 and 19, 2017, respectively. ER 577, 60.

The proposed Rules complied with TSCA's mandate to take a comprehensive approach to chemical risk evaluation. EPA explained in the proposed Prioritization Rule that, "in response to clear statutory directives," it would "designate the priority of a 'chemical substance,' as a whole," rather than "a specific use or subset of uses of a chemical substance." ER 581. In the proposed Risk Evaluation Rule, EPA likewise construed TSCA to require it to conduct risk

evaluations on "the chemical substance," "not [on] individual conditions of use." ER 63. EPA's focus on the total risk posed by each chemical informed critical aspects of the proposed Rules.

First, the proposed Rules required EPA to consider during both prioritization and risk evaluation "*all* known, intended, and reasonably foreseen activities associated with the subject chemical substance," i.e., "*all* … activities that constitute the conditions of use within the meaning of [the statutory definition]." *Id.* (emphases added); *see* ER 582, 588. EPA applied the requirement to evaluate all of a chemical's conditions of use to both EPA-initiated and manufacturer-requested risk evaluations. ER 60, 75-76. As a result, the proposed Risk Evaluation Rule required manufacturers requesting risk evaluations to provide EPA with "all [reasonably available] information that is necessary for EPA to conduct a risk evaluation addressing all the circumstances that constitute [the chemical's] conditions of use." ER 74.

Second, the proposed Risk Evaluation Rule required EPA to make a single, final risk determination of whether "the chemical substance presents an unreasonable risk of injury." ER 78, 63.

B. Influence of Dr. Nancy Beck over the final Framework Rules

Until at least April 12, 2017, EPA continued to interpret TSCA as requiring risk evaluations to "encompass all" of a chemical's conditions of use, and relied on

that interpretation in denying several citizen petitions under TSCA. *See* 82 Fed. Reg. 17,601, 17,603 (Apr. 12, 2017).

Shortly thereafter, however, the Trump Administration appointed Dr. Nancy Beck as Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention, which oversees the TSCA program. Since joining EPA in late April 2017, Dr. Beck has been the senior political appointee under the Administrator responsible for all aspects of EPA's implementation of TSCA. For the five years immediately before joining EPA, Dr. Beck was the Senior Director for Regulatory Science Policy at Respondent-Intervenor American Chemistry Council (ACC). MA 63.[4] A registered lobbying organization, ACC is the principal advocacy association representing the nation's largest and most influential chemical manufacturers. *See* MA 53, 67-68; ER 82.

As one of ACC's chief advocates regarding EPA's implementation of TSCA, Dr. Beck presented ACC's recommendations for the Framework Rules at an EPA public meeting on August 9, 2016, and signed ACC's August 2016 comments elaborating on its desired approach for the Rules. ER 79, 82. ACC and Dr. Beck urged EPA to focus on subsets of chemicals' conditions of use in its risk

[4] Petitioners use "MA" to refer to the Motion Appendix (ECF No. 43-2) filed with their Motion to Complete the Administrative Records. The Motion requests that the Court compel EPA to complete the administrative records with the documents identified in paragraphs 3 through 20 of the Marks Declaration, as well as additional documents that EPA omitted from its certified records.

evaluations. ER 86; *see also* MA 13, 17-18 (showing Dr. Beck's participation in a November 2016 meeting at the Office of Management and Budget at which ACC recommended that EPA not evaluate all conditions of use and instead focus on those uses "that present the highest likelihood of potential concern"). ACC's March 2017 comments on the Framework Rules, written while Dr. Beck remained at ACC, repeated the same positions as Dr. Beck's previous comments, including that EPA need not "include 'all' conditions of use in any particular risk evaluation." ER 137; *see* ER 606-07. Because of this prior advocacy on ACC's behalf, EPA's ethics office "advised" Dr. Beck that she "cannot participate in any meetings, discussions, or decisions that relate to any individual ACC comment nor attend any meeting at which ACC is present." MA 88.

Nonetheless, after Dr. Beck's arrival at EPA, the Agency abruptly reversed its interpretation of TSCA's requirements. The final Framework Rules upend EPA's prior approach to risk evaluations and significantly narrow the Agency's interpretation of the meaning of "the conditions of use." This altered approach ignored recommendations and concerns raised by career agency staff. *See* MA 25-27, 29-30. Many of the changes to the proposed Rules mirror ACC's specific requests, in many instances word for word. *See* MA 528-539.

C. The final Rules

The Framework Rules reject the comprehensive, substance-based approach of the proposed Rules.

First, EPA now asserts in the Risk Evaluation Rule that TSCA grants EPA "discretion" to exclude conditions of use from its risk evaluation of a chemical. ER 4. The Rule establishes no criteria for such exclusions. This pick-and-choose interpretation extends to the Rule's provisions allowing manufacturers to request risk evaluations limited to the conditions of use they wish to include. 40 C.F.R. § 702.37(b)(3); *see* ER 12.

Second, the Risk Evaluation Rule allows EPA to conduct piecemeal risk evaluations for a chemical, without determining whether the "chemical substance" poses an unreasonable risk. Instead, the Rule directs EPA to determine whether individual conditions of use in isolation pose unreasonable risks. 40 C.F.R. §§ 702.47 (EPA "will determine whether the chemical substance presents an unreasonable risk … *under each condition of uses* [sic] within the scope of the risk evaluation" (emphasis added)), 702.49(d); *see* ER 19.

Third, the Framework Rules rewrite the statutory definition of "conditions of use" to omit consideration of a chemical's ongoing and future uses and related disposals if manufacturing, processing, and distribution for those specific uses are no longer occurring. ER 4-5, 31. EPA misleadingly labels these omitted activities

"legacy uses," "associated disposal," and "legacy disposal." ER 4-5.

The Rules also limit EPA's ability to collect and consider reasonably available information necessary to inform its decisions under TSCA.

III. Risk evaluation actions to date

In December 2016, EPA selected the first ten chemicals to undergo risk evaluations under the amended TSCA and began those evaluations. 81 Fed. Reg. 91,927 (Dec. 19, 2016); *see* 15 U.S.C. § 2605(b)(2)(A). EPA released the scopes for these ten chemicals contemporaneously with the final Framework Rules. MA 520-22. The scopes rely on EPA's revised interpretations of TSCA incorporated into the Framework Rules. *See* 82 Fed. Reg. 31,592, 31,593 (July 7, 2017).

STANDARD OF REVIEW

The standard set forth in the Administrative Procedure Act applies to the Court's review of EPA rules implementing TSCA. 15 U.S.C. § 2618(c)(1). Under this standard, courts must "hold unlawful and set aside" agency action and conclusions "found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2).

When reviewing whether an agency's interpretation of a statute is lawful, the Court follows the test established in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *City of L.A. v. U.S. Dep't of Commerce*, 307 F.3d 859, 868 (9th Cir. 2002). If Congress has spoken directly to

the precise question at issue, the Court must give effect to Congress's unambiguously expressed intent. *Chevron*, 467 U.S. at 843 & n.9; *Akhtar v. Burzynski*, 384 F.3d 1193, 1198 (9th Cir. 2004). If the statute is silent or ambiguous, a court will defer to an agency's reasonable interpretation. *Chevron*, 467 U.S. at 843 & n.9.

In addition, agency action is arbitrary and capricious where an agency "entirely fail[s] to consider an important aspect of the problem" or fails to articulate a "'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). A court's review of agency action, while "deferential," must be "thorough, probing, [and] in-depth." *Ranchers Cattleman Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric*., 415 F.3d 1078, 1093 (9th Cir. 2005) (internal quotation marks omitted).

SUMMARY OF ARGUMENT

1. EPA's claim of authority to exclude conditions of use and their resulting exposures from risk evaluations violates TSCA's plain text, structure, and purpose. The directive to "determine whether *a chemical substance* presents an unreasonable risk" requires an evaluation of the chemical's total risk. And the phrase "under *the* conditions of use" unambiguously means *all* of the chemical's

conditions of use. Several provisions of TSCA confirm Congress's intent. First, when Congress intended EPA to act on fewer than all conditions of use, it expressly provided for such action. Second, Congress created a narrow exception allowing EPA to regulate certain chemicals based on previously completed risk assessments limited to a subset of conditions of use; this exception confirms that the new law otherwise requires comprehensive risk evaluations. Third, TSCA specifies in detail how EPA is to prioritize chemicals and evaluate their risks, but does not provide EPA with any criteria to eliminate conditions of use. Moreover, excluding conditions of use will frustrate TSCA's purpose of preventing unreasonable risks to health by underestimating risk, especially to vulnerable subpopulations. EPA's interpretation fails under *Chevron* and reflects arbitrary and capricious reasoning.

2. EPA also asserts authority to find that individual conditions of use, standing alone, do not present an unreasonable risk, and that it need not make a risk determination for a chemical substance as a whole. EPA's use-by-use approach cannot be reconciled with TSCA's requirement that EPA make a single, holistic risk determination on "a chemical substance."

3. EPA unlawfully rewrites the definition of "conditions of use" to omit a chemical's current and future use and disposal if the chemical's manufacture, processing, and distribution for that specific use are not ongoing. Congress's

inclusion of "use" and "disposal" as "conditions of use" forecloses this construction. 15 U.S.C. § 2602(4). Moreover, Congress consciously allowed EPA to prioritize and evaluate chemicals that have not been manufactured in the ten years prior to passage of the TSCA amendments, i.e., chemicals that have *only* conditions of use ("use" and "disposal") that EPA claims it may omit from analysis. EPA's rewrite thus finds no support in the text or structure of TSCA.

4. The Framework Rules are inconsistent with EPA's duty to "take into consideration" all "reasonably available" information when prioritizing chemicals and conducting risk evaluations. 15 U.S.C. § 2625(k). For example, the Risk Evaluation Rule penalizes any "incomplete" public submissions, chilling public participation. The Rule also impermissibly limits the information manufacturers must provide when requesting a risk evaluation, allowing them to withhold relevant information about a chemical. These information-limiting provisions inhibit the scientifically sound decisions EPA is required to make under section 6.

5. Petitioners have standing to challenge the Framework Rules because their members face a credible threat of injury from EPA's unlawful approach to prioritizing chemicals and evaluating their risks. Petitioners also have informational standing to challenge the Risk Evaluation Rule, and some Petitioners have organizational standing to challenge that Rule.

ARGUMENT

I. The Framework Rules violate TSCA's mandate that risk evaluations consider all of a chemical's conditions of use

Under TSCA, EPA must conduct risk evaluations to determine whether "*a chemical substance* presents an unreasonable risk … under *the conditions of use*." 15 U.S.C. § 2605(b)(4)(A) (emphases added). This directive expresses Congress's clear intent that EPA evaluate the risks posed by "a chemical substance" as a whole, taking into account all circumstances comprising "the conditions of use" of the chemical.

Ignoring Congress's unambiguous direction, the Framework Rules grant EPA unfettered "discretion" to pick and choose which conditions of use it will include in each risk evaluation. ER 4-5. In other words, EPA claims authority to "exclude certain activities that EPA has determined to be conditions of use" from risk evaluations. ER 4.[5] The Risk Evaluation Rule codifies this pick-and-choose approach by providing that the scope of each evaluation will "include" only "[t]he

[5] To the extent the Prioritization Rule authorizes EPA to exclude conditions of use from consideration when designating a chemical as high- or low-priority, the Rule is likewise unlawful. *See* ER 31 (referring to EPA's "discretion to 'determine' the conditions of use" for each chemical); *compare* 40 C.F.R. § 702.9(f) (basing proposed low-priority designations on "the proposed conclusion that the chemical substance meets the definition of Low-Priority Substance … *under the activities that [EPA] determines constitute conditions of use*" (emphasis added)), *with* ER 588 (basing low-priority designations on consideration of "all uses that [EPA] determines constitute conditions of use").

condition(s) of use, as determined by the Administrator, *that the EPA plans to consider*," giving EPA carte blanche to exclude any conditions of use it chooses. 40 C.F.R. § 702.41(c)(1) (emphasis added). The Rule repeatedly refers to "the conditions of use *within* the scope of the evaluation," indicating that some conditions of use are outside the evaluation's scope. 40 C.F.R. §§ 702.41(a)(5), (a)(8), (a)(9), (c)(4)(i), (c)(4)(iii), (d)(2); 702.49(b), (c), (d) (emphasis added). Similarly, the Rule allows EPA to limit an evaluation requested by a manufacturer to those conditions of use "identified in the request," and other limited conditions of use that "warrant inclusion." *Id*. § 702.37(e)(3); *see id.* § 702.37(b)(3).

EPA points to a smorgasbord of potential exposure pathways it may exclude, while also leaving open the possibility of other exclusions as well. *See* ER 5 (asserting it may exclude a chemical's presence as an "impurity"), 183-85 (suggesting it may exclude use as an intermediate chemical during manufacturing, the incidental manufacturing of a chemical as a byproduct, and uses "where other agencies hold jurisdiction").

EPA's interpretation is not only contrary to the "particular statutory language at issue" and "the language and the design of the statute as a whole," *McCarthy v. Bronson*, 500 U.S. 136, 139 (1991) (quoting *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988)), but also frustrates TSCA's purposes by ignoring exposures and underestimating risks posed by chemicals, *see Wilderness Soc'y v.*

U.S. Fish & Wildlife Servs., 353 F.3d 1051, 1060 (9th Cir. 2003) (en banc). If EPA excludes conditions of use during prioritization and risk evaluations, it cannot fulfill TSCA's command to determine whether "a chemical substance" poses an unreasonable risk to health or the environment. 15 U.S.C. § 2605(b)(4)(A). The Court must give effect to Congress's "unambiguously expressed intent" by setting aside the provisions of the Framework Rules that reflect EPA's illegal approach. *Chevron*, 467 U.S. at 843.

A. TSCA's plain language requires EPA to include all conditions of use in prioritization and risk evaluations

The starting point for construing TSCA "is the language of the statute itself." *Grp. Life & Health Ins. Co. v. Royal Drug Co.*, 440 U.S. 205, 210 (1979).

1. TSCA requires priority designations and risk evaluations to focus on "a chemical substance" as a whole

Congress consistently used the phrase "a chemical substance" to describe the object of priority designations and risk evaluations. 15 U.S.C. § 2605(b)(1)-(4), (i) (using the phrase fourteen times). This language requires EPA to consider all hazards and exposures that contribute to the total risk presented by the chemical substance as a whole.

This whole-substance focus begins during prioritization. The definitions of high- and low-priority substances make clear that it is the "substance" that receives the designation, not selected uses. *See id.* § 2605(b)(1)(B). As EPA recognized in

the Prioritization Rule, "[t]he statute is clear that EPA is to designate the priority of the 'chemical substance'—not a condition of use for a chemical substance." ER 31 (citing 15 U.S.C. § 2605(b)(1)(A)).

EPA must also conduct risk evaluations on "a chemical substance" as a whole. For example, TSCA provides that "[u]pon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on *the substance*." 15 U.S.C. § 2605(b)(3)(A) (emphasis added). Similarly, the statute directs EPA to determine either that "*a chemical substance* presents" or "does not present an unreasonable risk." *Id.* § 2605(i)(1)-(2) (emphasis added). Congress also uses the phrase "a chemical substance" or "chemical substances" in many other places in TSCA's risk evaluation provisions. *See, e.g.*, *id.* § 2605(b)(4)(G) (setting deadlines for completing evaluation for "a chemical substance"), (b)(2)(A), (b)(2)(B), (b)(3)(A), (c)(1).

Together, these provisions show that "the statute requires" EPA to determine "whether a chemical substance, as a whole, presents an unreasonable risk or [sic] injury." ER 63-64. As EPA previously concluded, an interpretation allowing the Agency to evaluate "merely a subset of individual uses" is "a strained reading" of section 6(b). *Id.*

2. The phrase "the conditions of use" means *all* conditions of use

By requiring EPA to determine whether a chemical substance presents an unreasonable risk "under *the* conditions of use," 15 U.S.C. § 2605(b)(4)(A) (emphasis added), TSCA is unambiguous: EPA's evaluation must include *all* conditions of use of the chemical. The "definite article 'the' particularizes the subject which it precedes," in contrast to the "indefinite or generalizing force of 'a.'" *In re Cardelucci*, 285 F.3d 1231, 1234 (9th Cir. 2002) (quoting Black's Law Dictionary 1477 (6th ed. 1990)). When "the" precedes a collective or plural noun, it is equivalent to "all." *E.g.*, *Dutcher v. Matheson*, 840 F.3d 1183, 1194 (10th Cir. 2016); *Kaufman v. Allstate N.J. Ins. Co.*, 561 F.3d 144, 155 (3d Cir. 2009); *Frazier v. Pioneer Americas LLC*, 455 F.3d 542, 546 (5th Cir. 2006). Accordingly, the phrase "the conditions of use" means *all* conditions of use.

When Congress intended EPA to act on fewer than all of a chemical's conditions of use, it used different words to convey that intent. *See SEC v. McCarthy*, 322 F.3d 650, 656 (9th Cir. 2003). Congress allowed EPA to grant exemptions from risk management rules for "a specific condition of use" of a chemical, 15 U.S.C. § 2605(g)(1); directed EPA to consider reasonably available alternatives when deciding whether to ban or restrict "a specific condition of use," *id.* § 2605(c)(2)(C); and permitted EPA to allow test marketing for "specific conditions of use" of new chemicals in some circumstances, *id.* § 2604(h); *see also*

id. § 2613(b)(4)(B)(i) (referring to "a specific condition of use"). The Court "must assume that this difference in language is legally significant." *Spencer Enters., Inc. v. United States*, 345 F.3d 683, 689 (9th Cir. 2003).

B. EPA's conclusion that it may exclude conditions of use is contrary to TSCA's structure

Because courts "construe statutes, not isolated provisions," *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (internal quotation marks omitted), "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (internal quotation marks omitted).

1. EPA's pick-and-choose approach cannot be squared with the overall structure of TSCA

As EPA concluded in its proposed Risk Evaluation Rule, that TSCA "provides no criteria for EPA to apply" shows that the Agency does not have "license to choose among conditions of use." ER 64. The precision with which Congress prescribed EPA's implementation of section 6 supports this reading. Section 6 lays out detailed directions for EPA. *See* 15 U.S.C. § 2605(b)(1)(A) (mandating considerations for priority designations), (b)(4)(D) (identifying risk factors to include in a risk evaluation's scope), (b)(4)(F)(i)-(v) (detailing requirements for conducting risk evaluations); *see also id.* § 2605(a) (specifying possible risk management measures). These provisions indicate that Congress did

not mean to allow EPA to exclude conditions of use from prioritization or risk evaluation without any criteria or instruction. *Cf. NRDC, Inc. v. EPA*, 863 F.2d 1420, 1432 (9th Cir. 1988) (invalidating regulatory procedure that "is wholly silent as to what factors the agency is to consider in granting exceptions" and provides "no discernible standard [for] limit[ing] th[at] discretion").

Indeed, when Congress intended EPA to exercise discretion under TSCA, it said so explicitly. *See, e.g.*, 15 U.S.C. §§ 2613(f) (granting EPA "[d]iscretion" in handling claims to protect confidential information), 2608(a) (instructing EPA, if it "determines, in the Administrator's discretion," that an unreasonable risk may be prevented under a federal law administered by another agency, to notify the agency), 2608(b), 2605(b)(4)(E)(iv)(II). That Congress purposefully included the language of discretion "in one section of the statute but omit[ted] it in another section of the same Act" shows that Congress did not intend EPA to use discretion to pick and choose which conditions of use to consider in prioritization and risk evaluation. *Hernandez v. Ashcroft*, 345 F.3d 824, 834 (9th Cir. 2003) (quoting *Andreiu v. Ashcroft*, 253 F.3d 477, 480 (9th Cir. 2001) (en banc)).

Underscoring that the pick-and-choose approach is inconsistent with TSCA's structure is EPA's suggestion that it may exclude "[u]ses where other agencies hold jurisdiction." ER 5. Congress is plainly aware, for example, that the Occupational Safety and Health Administration (OSHA) also has jurisdiction over

worker safety, but section 6(b), when read with the definition of "potentially exposed or susceptible subpopulation," specifically requires EPA to evaluate the risks to workers. 15 U.S.C. §§ 2602(12), 2605(b)(4)(A). Further, section 9(c) permits concurrent EPA and OSHA regulation over working conditions. *See id.* § 2608(c). And, section 9 expressly contemplates that EPA may—only after it determines that a chemical presents an unreasonable risk—determine that the risk "may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered" by EPA. *Id.* § 2608(a). These provisions show that Congress intended EPA to evaluate all conditions of use, even those potentially under the jurisdiction of other agencies. Indeed, where Congress intended to exclude uses of a chemical because they fall under the jurisdiction of another agency, it did so expressly. *See id*. § 2602(2)(B) (excluding from the definition of "chemical substance" uses regulated by other agencies under statutes such as the Food, Drug, and Cosmetic Act).

Similarly, EPA suggests that it may exclude conditions of use for reasons that bear no relationship to risk. *See* ER 5, 183-85. Such exclusions violate TSCA's requirement that EPA evaluate a chemical's risk "without consideration of costs or other nonrisk factors." 15 U.S.C. § 2605(b)(4)(A).

2. TSCA's exception allowing certain partial risk evaluations confirms that comprehensive risk evaluations are the general rule

The express, limited exception Congress created to allow EPA to act on partial risk evaluations conducted prior to the 2016 TSCA amendments further confirms that Congress otherwise intended EPA to consider all conditions of use in risk evaluations. *See* 15 U.S.C. § 2625(*l*)(4). Section 26(*l*)(4) authorizes EPA to issue risk management rules for chemicals that, prior to the 2016 amendments, had been subject to partial risk evaluations based on a subset of conditions of use.[6] *Id.* Congress enacted this provision in direct response to concerns raised by EPA during the legislative process that partial risk evaluations were "simply not contemplated under the House and Senate bills." *See* MA 541. EPA noted that, absent this carve-out, the pending legislation would require EPA "to assess a chemical in its entirety, based on *all* conditions of use," and would preclude EPA from acting on its 2014 partial risk evaluations. *See* MA 540-42. Construing TSCA to allow EPA to conduct partial risk evaluations outside of this narrow carve-out, as the Framework Rules do, impermissibly renders section 26(*l*)(4) meaningless. *See Bilski v. Kappos*, 561 U.S. 593, 607-08 (2010). Although EPA now espouses a new view of this statutory language, its statement "to Congress …

[6] *E.g.*, trichloroethylene, 82 Fed. Reg. 7432, 7433 (proposed Jan. 19, 2017); methylene chloride and n-methylpyrrolidone, 82 Fed. Reg. 7464, 7465 (proposed Jan. 19, 2017).

at the very time it presented its own amendment to the Congress as one it urged for adoption … [is] more reliable." *United States v. One Bell Jet Ranger II Helicopter*, 943 F.2d 1121, 1126 (9th Cir. 1991).

C. Excluding conditions of use will frustrate TSCA's aim to prevent unreasonable risks to health from toxic chemicals

The meaning of statutory language "depends on context," including the statute's objectives. *Brower v. Evans*, 257 F.3d 1058, 1065 (9th Cir. 2001) (internal quotation marks omitted); *see Crandon v. United States*, 494 U.S. 152, 158 (1990). TSCA's overriding purpose is to eliminate "unreasonable risk[s] of injury to health or the environment" associated with chemicals, *see* 15 U.S.C. §§ 2601(b), 2605(a), by authorizing EPA to "look comprehensively at the hazards associated with the chemical," S. Rep. No. 94-698, at 2; *supra* p. 6. Congress amended TSCA to promote "effective implementation" of the 1976 law's objectives. *See* S. Rep. No. 114-67, at 2. Thus, the TSCA amendments reaffirm EPA's obligation to comprehensively evaluate the risks of chemicals, for example by defining "conditions of use" broadly to encompass a chemical's whole lifecycle and mandating that EPA protect vulnerable subpopulations. *See* 15 U.S.C. §§ 2602(4), 2605(b)(4)(A).

Preventing unreasonable risk from a chemical requires EPA to consider all sources and pathways of exposure. As one of EPA's risk assessment handbooks explains, individuals may be exposed to chemicals "through more than one

pathway. … [T]o achieve effective risk assessment and risk management decisions, *all* media and routes of exposure should be assessed." ER 248 (emphasis added). As public commenters explained, "a worker may be exposed to a chemical both at home and in the workplace, while an infant may be exposed to a chemical both through breast milk and through household dust." ER 253; *see also* ER 260. Additionally, an individual's exposure to a chemical through a single pathway (e.g., drinking water) may result from multiple uses of the chemical. *See* MA 29-30; ER 269, 272. "Even small exposures can add up over time to cause serious harm." ER 249. As EPA explained in the proposed Risk Evaluation Rule, if the Agency "were free to base its determination of whether a chemical substance, as a whole, presents an unreasonable risk … on merely a subset of individual uses, it could, for example, determine that a chemical substance with 10 known uses does not present an unreasonable risk of injury" after evaluating "a single one of those uses," while neglecting to evaluate other uses that may contribute to the chemical's risks. ER 63-64. This principle also explains why EPA must designate a chemical as high-priority if it lacks sufficient information to determine whether the chemical may present an unreasonable risk (including an unreasonable risk to vulnerable subpopulations). 15 U.S.C. § 2605(b)(2)(B). EPA cannot rule out the possibility that a chemical presents an unreasonable risk unless it has sufficient information on all conditions of use, because each condition of use

may contribute to the chemical's total risk.

For the same reasons, excluding uses undermines the TSCA amendments' express commitment to protecting "potentially exposed or susceptible subpopulations," such as children, the elderly, and workers, from unreasonable chemical risks. *See* 15 U.S.C. § 2605(b)(1)(B)(i), (b)(4)(A), (b)(4)(F)(i). These subpopulations are defined by their "greater susceptibility or greater exposure" to chemicals, which may lead them to be "at greater risk than the general population of adverse health effects from exposure to a chemical." *Id.* § 2602(12). They face greater harm from low-level exposures, and may have more frequent exposures, from more sources, over time than the general population. *See, e.g.*, ER 275, 278 (children have "unique vulnerabilities to toxic chemicals," especially from "chronic, low-dose exposures that may occur at [developmentally] significant times"), 280-81, 284-87 (communities reliant on subsistence fishing and "wild foods" may face greater exposure to pollutants), 289, 290-91 (bio-accumulation of toxic chemicals in fish may increase exposure to individuals reliant on a "traditional subsistence diet"); *see also* ER 262-63, 298. To assess exposures to these vulnerable subpopulations in "real-world situations," EPA must consider "the totality of exposures from multiple pathways." ER 323 (citing U.S. EPA, Guidelines for Human Exposure Assessment, Risk Assessment Forum, Peer Review Draft (2016)).

* * *

In sum, TSCA's text, structure, and purpose show that Congress spoke clearly to require EPA to include all conditions of use in making a priority designation and conducting a risk evaluation of a chemical substance.

D. EPA's asserted rationales in support of the pick-and-choose approach fail

1. The two statutory phrases EPA relies on do not grant it discretion to pick and choose

Neither of the two statutory phrases EPA plucks out of context grants it discretion to exclude conditions of use.

First, EPA's contention that the phrase "as determined by the Administrator" confers pick-and-choose authority is mistaken. *See* ER 4-5. This phrase merely confirms that EPA has a role in identifying the "circumstances" comprising a chemical's conditions of use under the statutory definition through factual investigation. *See* ER 4 (acknowledging that the "as determined by" phrase refers to a "largely … factual determination").

But EPA's role in "determin[ing]" the conditions of use is a limited one. The phrase "as determined by the Administrator" does not exist in a vacuum; the clause interrupts and modifies the rest of the definition. 15 U.S.C. § 2602(4). Thus, what EPA must "determine," i.e., identify by factual investigation, is bounded by the rest of the definition—the circumstances of a chemical's

"intended, known, or reasonably foreseen" manufacture, processing, distribution, use, and disposal. *See id*. The phrase "as determined by" thus provides no authority for EPA to circumvent the statute's clear definition. *See U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 631-32 (D.C. Cir. 2016) (rejecting reliance on statutory phrase "as determined by" to support "claim[ed] discretion"), *on reh'g en banc*, 671 F. App'x 822 (D.C. Cir. 2016), *and on reh'g en banc in part*, 671 F. App'x 824 (D.C. Cir. 2016).

Second, EPA cannot justify its pick-and-choose approach based on section 6(b)(4)(D), which requires EPA to "publish the scope of the risk evaluation …, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). The phrase "expects to consider," understood in its ordinary meaning, does not provide discretion to pick and choose among the conditions of use. *See* Oxford American Dictionary 609 (3d ed. 2010) ("expect" means to "[r]egard (something) as likely to happen"); *supra* p. 27 (Congress used the word "discretion" when it meant to grant discretion). To the contrary, the term indicates only that EPA must describe the conditions of use it has identified through its fact-gathering. As EPA stated in the proposed rule, section 6(b)(4)(D) is "best read as directing the Agency to identify the uses and other activities that it has determined constitute the conditions of use, not as a license to choose among conditions of

use." ER 64. If "expects to consider" were to grant EPA broad discretion to pick-and-choose and also modified all the preceding nouns, then EPA would also have broad discretion to exclude from the risk evaluation any hazards of the chemical (e.g., carcinogenic effects) that EPA chooses. But this interpretation is absurd.[7]

Moreover, contrary to EPA's assertions, TSCA's legislative history does not support the pick-and-choose approach. EPA relies heavily on a floor statement by a single senator to justify its interpretation, *see* ER 3, while ignoring a contradictory floor statement from four other senators, *see* 114 Cong. Rec. S3518-19 (daily ed. June 7, 2016). In light of the legislators' "contradictory account[s]," the statement of a single senator is not dispositive as to statutory meaning, especially when the statement is contrary to "clear statutory language." *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 942-43 (2017); *Milner v. Dep't of Navy*, 562 U.S. 562, 572 (2011).

Even if TSCA were ambiguous, EPA's interpretation of the phrases "as determined by" and "expects to consider" as giving it carte blanche to exclude conditions of use is patently unreasonable. This is especially so because EPA's asserted discretion would be exercised even before conducting the evaluation that

[7] Alternatively, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even modify "conditions of use." *See Barnhart v. Thomas*, 540 U.S. 20, 26 (2003); *Nw. Forest Res. Council v. Glickman*, 82 F.3d 825, 832 (9th Cir. 1996), *as amended on denial of reh'g* (May 30, 1996).

should answer how significant a risk the conditions of use actually present. If upheld, EPA's interpretation would give the Agency license to exclude *any* condition of use for *any* reason during (or even before) prioritization or risk evaluation. This irrational interpretation would undermine the integrity and protectiveness of those processes and cannot be squared with TSCA. Additionally, the pick-and-choose approach gives EPA license to implement TSCA in a manner wholly lacking in reasoned decision-making, rendering it arbitrary and capricious. *Cf. NRDC, Inc. v. EPA*, 863 F.2d at 1432.

2. EPA's view that it has unfettered discretion to exclude conditions of use is impermissible and lacks a rational basis

Implicitly conceding that Congress did not grant it unlimited discretion, EPA asserts that it intends to focus on evaluating "the conditions of use that raise greatest potential for risk." ER 3; *see* ER 180 (same); *see also* MA 17-18 (ACC handout urging EPA to limit risk evaluations to those conditions of use that "present the highest likelihood of potential concern"). EPA's non-binding intention cannot rescue the Framework Rules. First, no language in TSCA limits EPA to this "greatest potential for risk" focus. Nor does EPA point to any statutory terms that even arguably supply such a limitation.

Moreover, the Risk Evaluation Rule and the scopes for the first ten chemicals show that EPA intends to exclude conditions of use without any risk-based rationale (i.e., based on "nonrisk factors," *contra* 15 U.S.C. § 2605(b)(4)(A))

and despite evidence that they do in fact present a serious potential for risk. For example, EPA indicates that it will exclude conditions of use of 1,4-dioxane when it is manufactured incidentally as a byproduct, a criterion with no connection to the level of risk presented, *see* 75 Fed. Reg. 49,656, 49,676 (proposed Aug. 13, 2010) (EPA "does not believe byproducts inherently pose lower exposures or risks than other manufactured chemical substances"), and that EPA itself has concluded falls within TSCA's jurisdiction, *see* 76 Fed. Reg. 50,816, 50,832 (Aug. 16, 2011). This exclusion of byproduct uses means that 1,4-dioxane's presence in many "commercial and consumer products," such as paints, household cleaners and detergents, and textile dyes, will not be evaluated, although these uses may present meaningful risks for some populations. MA 157, 170; ER 367; *cf.* ER 701. These excluded uses illustrate that EPA's "greatest potential for risk" rationale does not actually govern its exclusions.

In any event, focusing on only those conditions of use that EPA deems pose "the greatest potential for risk" is itself inconsistent with TSCA. The statute's plain terms require consideration of all conditions of use, not just the riskiest conditions. *See supra* pp. 23-26. There would be no way for EPA to determine soundly which conditions of use pose the greatest potential for risk *before* beginning the evaluation whose purpose is to assess the risks of those conditions of use. And it would be unreasonable to interpret the statute as allowing EPA to

prioritize chemicals or conduct risk evaluations without considering risks from multiple (sometimes relatively low-dose) exposures to the same chemical. This exclusionary approach would prevent EPA from accurately evaluating total risks to vulnerable subpopulations like children, for whom low doses can pose significant risks, especially when they add up. *See supra* p. 32.

Likewise, EPA's "greatest potential for risk" theory is arbitrary and capricious because EPA has not provided a rational explanation to reconcile its pick-and-choose approach with TSCA's mandate to determine whether "a chemical substance" poses an unreasonable risk, including an unreasonable risk to vulnerable subpopulations, and to issue risk management rules to eliminate any such risks. *See State Farm*, 463 U.S. at 43.

Nor can EPA justify its pick-and-choose interpretation by reference to concerns about completing risk evaluations within "statutory deadlines." ER 3-4. This is not a legitimate excuse to disregard plain statutory language. *See Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1026 (9th Cir. 2007). In any event, EPA has not explained its turnaround from its factual conclusion in the proposed Rule that including all conditions of use would be "manageable given the statutory deadlines." ER 64.

II. EPA's use-by-use approach to risk determinations contravenes TSCA's requirement that EPA make a holistic risk determination for each chemical

EPA violates TSCA by asserting authority to determine the risk of individual conditions of use in isolation, not the chemical substance holistically. *See* 40 C.F.R. §§ 702.41(a)(9), 702.47, 702.49(d); ER 19. This aspect of the Risk Evaluation Rule flouts TSCA's command to determine whether "a chemical substance" presents an unreasonable risk, 15 U.S.C. § 2605(b)(4)(A), and defeats TSCA's purpose of preventing harms from toxic chemicals, *see supra* pp. 30-33. The holistic risk determination demanded by the statute must take into account that multiple exposures to the same chemical from different sources will increase risk. *See* 15 U.S.C. § 2605(b)(4)(F). If EPA considers each pathway to a chemical in isolation, as its Rule permits, it could determine that no single use poses an unreasonable risk, even where the totality of uses presents an unreasonable risk.

This use-by-use approach to risk determinations also cannot be squared with section 6(a), which requires EPA to issue a risk management rule if it determines that "any combination of" a chemical's "manufacture, processing, distribution in commerce, use, or disposal" presents an unreasonable risk. *Id.* § 2605(a). EPA cannot rule out the possibility that a combination of a chemical's conditions of use presents an unreasonable risk until after it has considered all of its conditions of use collectively. Sections 702.41(a)(9), 702.47, and 702.49(d) in the Risk

Evaluation Rule are thus contrary to TSCA and must be set aside.

Under some circumstances EPA may determine that a particular use of a chemical *does* present an unreasonable risk before completing its risk determination. *See* 15 U.S.C. § 2605(a). This is because a "single use" may "present[] an unreasonable risk of injury for the population as a whole or for a susceptible subpopulation … regardless of the risk posed by other uses." ER 66. If EPA finds that a single use creates an unreasonable risk of harm, TSCA allows EPA to act quickly to protect public health, whether or not it has completed a risk determination for all uses, as EPA acknowledges. ER 15; *see* 15 U.S.C. § 2605(a), (b)(4)(A).

The converse, however, is not true. *See supra* pp. 30-33. Because the Risk Evaluation Rule allows EPA to determine that specific uses of a chemical do not pose an unreasonable risk before completing a comprehensive determination of the risks posed by the chemical, the Rule is contrary to law. *See Chevron*, 467 U.S. at 842-43.

III. EPA has unlawfully rewritten the statutory definition of "conditions of use" to omit certain uses and disposals

EPA rewrites Congress's unambiguous definition of "conditions of use" to significantly narrow the conditions of use the Agency will consider when making priority designations and conducting risk evaluations. ER 4, 5, 31. In contravention of the statutory definition, *see* 15 U.S.C. § 2602(4), EPA concludes

that a chemical's ongoing use and disposal are *not* conditions of use if the chemical's manufacture, processing, or distribution for that specific use are not "prospective or on-going," ER 5. Moreover, EPA constricts the meaning of "disposal" to include only the one-time event when a chemical or product containing the chemical is placed in a landfill or other waste facility. Based on these contortions, EPA categorically omits from consideration three types of chemicals' conditions of use, which EPA misleadingly labels "legacy use," "associated disposal," and "legacy disposal." ER 4-5; *see* ER 31. This "rewriting [of TSCA's] unambiguous statutory terms" cannot stand. *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2445 (2014). Congress's clear definition controls the meaning of "conditions of use." *See Dig. Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 776 (2018); *United States v. Olson*, 856 F.3d 1216, 1223 (9th Cir. 2017).

A. A chemical's "conditions of use" include ongoing and future use and disposal under TSCA's plain language

TSCA's unambiguous text precludes EPA's conclusion that the term "conditions of use" ceases to apply to ongoing use and disposal once a chemical is no longer manufactured, processed, or distributed for a specific use. ER 4-5, 31. Although EPA asserts that TSCA is "ambiguous" and that "[n]o statutory text expressly addresses" the issue, ER 4, this is simply not so. A chemical's conditions of use include "the circumstances" under which the chemical is "known, or reasonably foreseen to be manufactured, processed, distributed in

commerce, *used, or disposed of*." 15 U.S.C. § 2602(4) (emphasis added). Because the definition uses a disjunctive "or" list, each lifecycle stage of a chemical, standing alone, is a condition of use, even if some of the chemical's lifecycle stages have been discontinued. *See, e.g.*, *Horne v. Flores*, 557 U.S. 433, 454 (2009). EPA's construction robs the words "use" and "disposal" of their clear, independent role in the statute. The Court should reject EPA's attempt to "manufacture ambiguity" out of TSCA's plain language. *Aragon-Salazar v. Holder*, 769 F.3d 699, 706 (9th Cir. 2014).

Each of the three categories EPA concludes are *not* conditions of use falls squarely within the plain meaning of the definition. First, what EPA confusingly labels "legacy uses" includes ongoing and future uses of a chemical that is no longer manufactured, processed, or distributed for those specific uses. ER 4. Such uses are "circumstances" under which that chemical is "known" or "reasonably foreseen to be … used." 15 U.S.C. § 2602(4). For instance, notwithstanding that asbestos insulation is no longer produced in the United States, asbestos still insulates homes and buildings, is thus still *used* as insulation, and can become airborne if disturbed through remodeling or renovation. MA 111, 114-15; *see* 54 Fed. Reg. 29,460, 29,472-73 (July 12, 1989).

Second, so-called "associated disposal" refers to future disposals of a chemical relating to uses for which the chemical "is no longer manufactured,

processed, or distributed." ER 4. This includes, for example, sending asbestos-containing debris from demolition of a building to a landfill. *See id*. Such disposals are "circumstances" under which a chemical is "known" or "reasonably foreseen to be … disposed of." 15 U.S.C. § 2602(4).

Third, so-called "legacy disposals" are "circumstances" under which a chemical is "known … to be … disposed of." *Id.* Contrary to EPA's assertion, these disposals are *ongoing*, not historical, activities. ER 4. "Disposal" of a chemical substance (including products containing that substance) is not a one-time occurrence when the substance or product is buried or placed in a landfill or other waste facility, but remains ongoing after the initial act of discard.

Although TSCA does not define "disposal," EPA previously defined the term in regulations implementing TSCA's requirement that EPA regulate disposal of a class of chemicals called polychlorinated biphenyls (PCBs). 15 U.S.C. § 2605(e); 40 C.F.R. § 761.3. EPA's regulations define disposal "very broadly to include any action that may be related to the ultimate disposition" of PCBs, including "accidental or intentional release of PCB[s] … to the environment." 43 Fed. Reg. 7150, 7150 (Feb. 17, 1978). EPA's "disposal" definition also includes "spills, leaks, and other uncontrolled discharges of PCBs as well as actions related to containing, transporting, destroying, degrading, decontaminating, or confining PCBs." 40 C.F.R. § 761.3. The ongoing activities of keeping the

chemical "contain[ed] … or confin[ed]" are much broader than a one-time event. *Id.*

That disposal is not a one-time occurrence is also reflected in EPA's inclusion of "leaks, and other uncontrolled discharges" in its definition of disposal under TSCA. *Id.* Under EPA's regulations, disposal remains ongoing because PCB-contaminated soil can present ongoing and future risks if the substance leaks out of the containment or waste facility. *See In re Newell Recycling Co.*, 8 E.A.D. 598, TSCA Docket No. VI-659C (E.A.B. 1999), *aff'd, Newell Recycling Co. v. U.S. EPA*, 231 F.3d 204, 207-08 (5th Cir. 2000) (affirming EPA's rejection of claim that "PCB disposal is a one-time event"). For example, in *Environmental Defense Fund, Inc. v. EPA*, EPA acknowledged that PCB-containing "industrial waste and discarded end use products … in landfill sites … constitute[] a potential source of new free PCBs" that can be "a direct source of contamination for wildlife and humans." 636 F.2d 1267, 1270 (D.C. Cir. 1980) (quoting EPA Support Document).

In short, disposal of a chemical continues after it has been placed in a waste facility, and is a condition of use. 15 U.S.C. § 2602(4). The Court must set aside EPA's conclusion to the contrary.

B. EPA's rewriting of the "conditions of use" definition is contrary to TSCA's structure and purpose

EPA's rewritten definition of "conditions of use" is inconsistent with the "overall statutory scheme" and purposes of TSCA. *See Brown & Williamson*, 529 U.S. at 133 (internal quotation marks omitted).

1. EPA's definition is at odds with TSCA's statutory scheme

First, EPA's interpretation ignores that when Congress amended section 6, it recognized that "inactive" chemicals could undergo prioritization and risk evaluation. As amended, section 8 of TSCA distinguishes between "active" chemicals, which had been manufactured or processed during the ten years prior to June 22, 2016, and "inactive" chemicals, which had not. 15 U.S.C. § 2607(b)(4)(A)(i)-(iii). In contrast, section 6 refers simply to "chemical substances," without reference to the date when the chemicals were last manufactured or processed. *Id.* § 2605. As the Senate Report accompanying an early version of the amended TSCA acknowledged, "there may be exposures of concern from substances that are not currently or no longer in commerce, and the section provides EPA authority to prioritize inactive substances that meet certain criteria." S. Rep. No. 114-67, at 11. The Court must presume that, by including the active/inactive distinction in section 8, but omitting the distinction in section 6, Congress acted intentionally. *See Russello v. United States*, 464 U.S. 16, 23 (1983). Thus, Congress intended EPA to prioritize, conduct risk evaluations on,

and regulate chemicals with no recent manufacture or processing. Indeed, EPA itself rejected commenters' suggestion that EPA should not prioritize inactive chemicals. ER 32, 659. EPA's limited definition is at odds with Congress's deliberate scheme.

Second, EPA's interpretation would result in inconsistent treatment of identical activities based solely on whether manufacture or distribution is ongoing, a criterion that appears nowhere in section 6. For instance, under EPA's interpretation, a chemical's use in insulation constitutes a "condition of use" if the chemical is currently manufactured, processed, or distributed for use in insulation, but not otherwise. *See* ER 4; *compare* MA 229 (including as "condition of use" use of HBCD as insulation), *with* MA 114-115 (excluding from risk evaluation use of asbestos as insulation). This is so even if both uses present similar risks to public health. Omitting exposure scenarios from risk evaluations or prioritization decisions based on the happenstance of whether manufacturing, processing, or distribution for that specific use is ongoing is inconsistent with TSCA, as it involves considering a "nonrisk factor[]," just what TSCA prohibits. 15 U.S.C. § 2605(b)(1)(B), (b)(4)(A). These categorical omissions are capricious, in violation of TSCA.

2. EPA's rewritten definition defeats TSCA's core purpose

EPA's three categorical omissions from the "conditions of use" definition, *see* ER 5, undermine TSCA's core aim to prevent unreasonable risks to health and the environment from toxic chemicals. *See* 15 U.S.C. §§ 2601(b), 2605(a)-(b). This statutory purpose is reflected both in the requirement that EPA regulate a chemical's use or disposal if either presents an unreasonable risk, and in EPA's broad authority to restrict "any manner or method" of a chemical's "use" or "disposal." *Id.* § 2605(a)(5)-(6). EPA's impermissible rewriting of the "conditions of use" definition will prevent it from making scientifically sound and health-protective decisions relating to priority designations and risk evaluations. Ongoing use and disposal of chemicals can pose significant risks that EPA must consider, even if the chemicals are no longer made, processed, or distributed for those uses.

EPA's ongoing risk evaluation of asbestos illustrates this point. Asbestos is no longer mined in the United States, few asbestos-containing products are still being imported, MA 111, and most asbestos-containing products are no longer being made, processed, or distributed. Yet large numbers of asbestos-containing products previously manufactured remain in use, including building materials such as insulation and flooring, and certain vehicle equipment. MA 114; *see also* MA 114-15 (identifying many discontinued asbestos-containing products with ongoing use and exposure, including floor tile, roofing felt, pipeline wrap, and more).

Disposal of asbestos resulting from demolition, repair, or renovation of built structures or vehicle recycling is extensive, with disposal volumes totaling 25.6 million pounds in 2015. MA 116-17. Indeed, "the death rates from asbestos-caused diseases have remained constant," in part because of the "devastating health impact of asbestos in situ." ER 385. EPA's construction of "conditions of use" allows the Agency to ignore these health-threatening exposures in its risk evaluation. *See* MA 34 (Department of Health and Human Services urging EPA not to exclude "legacy uses" of asbestos, because such uses create "'new' hazardous exposure[s]" that pose significant risks to "fire fighters or building demolition [workers]").

Omitting ongoing use and disposal of chemicals no longer manufactured for those uses will also plague EPA's prioritization decisions. For example, when EPA considers whether to designate lead as high-priority, its analysis would be significantly under-inclusive if it omitted ongoing uses of lead-containing products—e.g., lead paint and lead-containing water pipes—that are no longer manufactured, but account for a substantial source of exposure to individuals. *See* 81 Fed. Reg. 60,304, 60,305 (proposed Sept. 1, 2016) (quoting CDC statement that "[l]ead-based paint and lead contaminated dust are the most hazardous sources of lead for U.S. children"); 56 Fed. Reg. 26,460, 26,470 (June 7, 1991) (contaminated drinking water contributes significantly to overall lead exposures); ER 699. EPA's

erroneous omissions from lead's "conditions of use" would render its priority designation for lead grossly inadequate. Such omissions are at odds with the purposes of the 2016 TSCA amendments, which require consideration of populations with special vulnerabilities to chemicals, such as children.

C. EPA's contention that the "conditions of use" definition applies only prospectively is unreasonable

EPA's only justification for these categorical omissions is its specious contention that TSCA is "better interpreted to focus on the prospective flow of the chemical substance." ER 5.

First, as explained above, so-called legacy use, associated disposal, and legacy disposal are in fact ongoing and therefore prospective circumstances. *Supra* pp. 41-44.

Second, EPA's reliance on the passive infinitive phrase "to be" in the "conditions of use" definition is misguided. The definition plainly encompasses circumstances under which a chemical "is … *known* … to be … used, or disposed of." 15 U.S.C. § 2602(4) (emphasis added). The verb "to be" in this context describes a state of existence, i.e., that those circumstances of use and disposal are known to exist. For instance, lead pipes are "known to be used" in water distribution systems. This is true regardless of whether lead pipes continue to be manufactured or distributed.

Third, EPA's suggestion that it may have limited authority under TSCA to

regulate use and disposal of discontinued products is both incorrect and irrelevant to the scope of risk evaluations conducted under section 6. ER 4. As discussed above, section 6(a) authorizes EPA to address risks from ongoing use and disposal of chemicals and products containing chemicals even in the absence of their ongoing manufacture, processing or distribution. 15 U.S.C. § 2605(a)(5)-(6).

Moreover, the possibility that EPA might identify an unreasonable risk that it lacks the tools to address, but that may be controlled by another agency, is not a valid reason to omit so-called legacy uses, associated disposal, and legacy disposal from risk evaluations and priority designations. TSCA section 9 expressly provides that, if EPA determines that a chemical presents an unreasonable risk that "may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by [EPA]," then EPA "shall" notify the other agency and ask whether the other agency will address the risk. *Id.* § 2608(a). The trigger for EPA to notify another agency under section 9(a) is a determination by EPA of unreasonable risk—a determination that can be made only *after* conducting a risk evaluation. *Id.* Congress thus anticipated that EPA's section 6(b) risk evaluations would include consideration of chemical exposures that may be most appropriately regulated by other agencies. EPA's approach would frustrate this deliberate statutory structure. *See supra* pp. 26-29.

Fourth, contrary to EPA's contention, *see* ER 5, the general presumption

against construing a statute to be retroactive has no application to the question of statutory interpretation at issue. EPA's priority designations and risk evaluations do not "impair the rights a party possessed" in the past, "impose new duties with respect to transactions already completed," or impose any liability whatever. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994).

In sum, considering the plain text of the "conditions of use" definition, the term's place in the statutory scheme, and TSCA's purposes, Congress unambiguously intended "conditions of use" to include ongoing and future uses and disposals of a chemical, even in the absence of ongoing manufacture, processing, and distribution for all or specific uses. EPA's categorical omission of so-called "legacy use," "associated disposal," and "legacy disposal" is unlawful and arbitrary. *See Chevron*, 467 U.S. at 842-43.

IV. The Framework Rules are inconsistent with EPA's obligation to base decisions on "reasonably available" information

TSCA requires EPA to consider all "reasonably available" information relating to a chemical when making prioritization decisions and conducting risk evaluations. 15 U.S.C. § 2625(k). The Framework Rules, however, preclude this consideration. The Prioritization Rule defines "reasonably available information" as "information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines … for prioritization and risk evaluation." 40 C.F.R. § 702.3; *id.* § 702.33 (same definition in Risk Evaluation

Rule, but limited to risk evaluation deadlines). But the Rules include provisions that will prevent EPA from obtaining and developing the reasonably available information it needs—and is required to consider—to make legally and scientifically sound decisions under section 6. EPA also failed to consider how these provisions will inhibit its ability to develop needed information, "an important aspect of the problem." *State Farm*, 463 U.S. at 43.

A. The Risk Evaluation Rule will impermissibly chill the sharing of information by penalizing "incomplete" submissions by the public

Public participation plays a central role in EPA's efforts to obtain "reasonably available" information for risk evaluations. For example, EPA must provide notice of and allow public comment on draft risk evaluations. 15 U.S.C. § 2605(b)(4)(H); *see* 40 C.F.R. § 702.49(a). EPA also "encourage[s]" the public to provide comments and relevant information concerning manufacturers' requests for risk evaluations. 40 C.F.R. § 702.37(e)(4). Yet the Risk Evaluation Rule will deter public participation by placing commenters at peril of criminal punishment and civil penalties for submitting "incomplete" information. *Compare id.* § 702.31(d) (prohibiting "[s]ubmission to EPA of inaccurate, *incomplete*, or misleading information pursuant to a risk evaluation" (emphasis added)), *with* ER 73 (proposing penalties solely for incomplete submissions by manufacturers). This exceeds EPA's statutory authority and is unconstitutionally vague.

TSCA authorizes EPA to penalize only the "fail[ure] or refus[al] to comply

with any requirement of [TSCA] or any rule promulgated, order issued, or consent agreement entered into" under the law. 15 U.S.C. § 2614(1). TSCA does not "require[]" members of the public to provide information to EPA. Thus, because 40 C.F.R. § 702.31(d) prohibits and threatens to penalize some voluntary information-sharing with EPA, it exceeds EPA's statutory authority and is invalid. *See City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013). It is also arbitrary and capricious for EPA to punish the public's submission of purportedly "incomplete" information, when the accumulated information EPA receives from individual commenters may well illustrate hazard or exposure patterns that would not come to light absent multiple submissions containing parts of the information. *Cf. NRDC, Inc. v. Pritzker*, 828 F.3d 1125, 1140 (9th Cir. 2016) (holding that agency acted contrary to law where it failed to consider how its choice to require "conclusive data" would result in underprotection of marine mammals by excluding potentially meaningful information).

In addition, by threatening members of the public with criminal and civil liability for providing incomplete information, section 702.31(d) runs afoul of the constitutional requirements of due process. A federal restriction violates due process protections when it is "so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." *Johnson v. United States*, 135 S. Ct. 2551, 2556 (2015). To

withstand scrutiny, section 702.31(d) requires the highest level of clarity because it touches on First Amendment activities of speech and petitioning the government, and subjects violators to criminal penalties. *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982); *cf. Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (First Amendment protects petitioning).

Section 702.31(d) fails to meet this stringent standard. Members of the public and interested organizations, including Petitioners, would like to submit comments during EPA's TSCA risk evaluations. *Cf.* ER 442-80 (commenting on EPA's initial assessments under TSCA for three flame retardant clusters). But the Rule imposes criminal and civil liability for providing "incomplete" information, while providing no guidance regarding what would make a submission complete. That is unlawfully vague. *See State v. Mark Marks, P.A.*, 698 So. 2d 533, 534 (Fla. 1997) (statute criminalizing submission of "incomplete" demand letters is unconstitutionally vague for absence of guidance on meaning of "complete"); *cf. United States v. Crop Growers Corp.*, 954 F. Supp. 335, 345 (D.D.C. 1997) ("[W]here a statute or regulation imposes *no* duty whatever to disclose information, due process concerns require that criminal liability not be based on omission of such information." (citing *United States v. Murphy*, 809 F.2d 1427, 1431 (9th Cir. 1987))).

The Rule's lack of clarity will not only subject individuals to arbitrary enforcement, it will "inevitably lead citizens to steer far wider of the unlawful zone … than if the boundaries of the forbidden areas were clearly marked." *See Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972) (internal citations and quotation marks omitted). This chilling effect is unconstitutional. It will also undermine TSCA's intent by depriving EPA of information potentially relevant to its risk evaluations that would be "reasonably available," but for the vague threat of penalties.

Further, EPA did not consider the consequences of penalizing "incomplete" submissions, and did not even acknowledge that it had vastly expanded potential criminal liability as compared to the proposed rule. *See* ER 1-28. Imposing criminal and civil penalties without discussing these issues is arbitrary and capricious. *See Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1142-43 (9th Cir. 2015) (rejecting agency action where EPA did not "'cogently explain why it has exercised its discretion in a given manner'" (quoting *State Farm*, 463 U.S. at 48)).

B. The Framework Rules impermissibly use the factors in TSCA section 26(h) to screen, rather than weigh, information

The Risk Evaluation Rule also violates TSCA by limiting the information manufacturers must submit when requesting a risk evaluation to "[s]cientific information [that is] consistent with the scientific standards in 15 U.S.C. 2625(h)."

40 C.F.R. § 702.37(b)(6). Section 26(h) requires that when EPA makes "a decision based on science," it must "consider as applicable" five factors to guide its decisions about the reliability of information. 15 U.S.C. § 2625(h). These factors include "the extent to which the information is relevant for [EPA's] use in making a decision about a chemical"; the "degree of clarity and completeness" with which the underlying data and analyses are documented; and "the extent to which the variability and uncertainty in the information … are evaluated and characterized." *Id*.

Section 702.37(b)(6) violates TSCA. It is both inconsistent with section 26(h) and contrary to section 26(k)'s mandate that EPA consider "reasonably available" information. *See* 15 U.S.C. § 2625(k).

First, section 702.37(b) impermissibly converts the section 26(h) considerations *EPA* must apply when weighing information into threshold requirements *manufacturers* must use to screen and limit the information they are permitted to submit to EPA. Nothing in the plain text of section 26(h) indicates that the factors are bright-line criteria for withholding information from EPA. To the contrary, each factor includes the phrase "degree of" or "extent to which," without identifying any threshold that would be disqualifying. This shows that Congress intended these factors to help EPA assess the weight information should be given based on its relative scientific reliability, not to create minimum

thresholds of reliability below which information must be withheld from EPA altogether. *Cf.* 15 U.S.C. § 2625(i) (directing EPA to make decisions "based on the weight of the scientific evidence"). EPA's conversion of these weight-of-the-evidence factors into a screening tool defies Congress's unambiguous intent.

Second, directing manufacturers to withhold information *the manufacturer decides* is not "consistent with" section 26(h) will prevent EPA from considering information relating to the chemical that is "reasonably available," in violation of section 26(k). For example, a manufacturer could decide that the documentation of "data, assumptions, … and analyses employed to generate the information" does not rise to the "degree of clarity and completeness," *id*. § 2625(h)(3), that makes it subject to disclosure under the Rule, 40 C.F.R. § 702.37(b)(6).[8] The withheld data, even if less than perfectly clear or complete, might have added to EPA's body of knowledge about the chemical. For this reason, section 702.37(b)(6) violates section 26(k)'s mandate that EPA consider reasonably available information. *Cf. Pritzker*, 828 F.3d at 1140 (rejecting agency's decision to rely on "screening criteria" that required "conclusive data" where such data were extremely difficult to obtain).

[8] EPA provided no discernible standards for what it would mean for information to be "consistent with" "the degree of clarity" or any of these other weighing factors.

The Prioritization Rule similarly incorporates an unlawful information screen. It states that during the prioritization process, EPA "expects to consider sources of information … consistent with the scientific standards in [section 26(h)]." 40 C.F.R. § 702.9(b). Just as EPA violated TSCA by directing manufacturers to withhold information that does not meet the section 26(h) "standards," EPA violated TSCA by erecting a "screen" that excludes some reasonably available information from EPA's prioritization process—rather than allowing EPA to weigh that information.

C. The Risk Evaluation Rule unlawfully and arbitrarily permits manufacturers to determine what information is relevant when requesting a risk evaluation

The Risk Evaluation Rule permits a manufacturer to withhold information critical to EPA's comprehensive evaluation of a chemical, if the manufacturer decides the information is not relevant to the specific conditions of use it is asking EPA to evaluate. Under the Rule, manufacturers must submit only "information that is relevant to whether the chemical substance, under the circumstances *identified by the manufacturer(s)*, presents an unreasonable risk." 40 C.F.R. § 702.37(b)(4) (emphasis added). This provision is contrary to TSCA and arbitrary and capricious.

To the extent the Rule allows EPA to limit risk evaluations to the conditions of use in the manufacturer's request, it rests on a faulty legal premise. As shown

above, risk evaluations must address all of a chemical's conditions of use. *See supra* pp. 23-26. Without information on all conditions of use, EPA cannot conduct a full evaluation.

Allowing manufacturers to withhold information about chemicals also flouts the requirement that EPA base the requested risk evaluations on "reasonably available" information. 15 U.S.C. § 2625(k). Relevant information about a chemical's conditions of use in the manufacturer's possession is plainly "reasonably available." *Id.* Consistent with the proposed rule, ER 74, EPA must require manufacturers requesting risk evaluations to submit all such relevant information for all of a chemical's conditions of use.

The Rule is also arbitrary and capricious, for two reasons. First, EPA has given no justification for its choice to allow manufacturers to withhold information in their possession relevant to EPA's risk evaluations. *See Arrington v. Daniels*, 516 F.3d 1106, 1114 (9th Cir. 2008). Second, it is irrational to allow manufacturers to withhold relevant and reasonably available information from their risk evaluation requests, while requiring general public commenters to provide "complete" information or risk civil and criminal penalties. *See supra* pp. 52-55.

D. EPA must consider during prioritization whether it has adequate information to conduct a risk evaluation

The Prioritization Rule does not require EPA to consider during the prioritization process whether it has adequate information about a chemical to conduct a risk evaluation; rather, EPA will consider only whether it has sufficient information "for purposes of prioritization" alone. 40 C.F.R. § 702.5(e); *see id.* § 702.5(b) (similar).[9] This limitation cannot be reconciled with the "reasonably available information" requirement. *See* 15 U.S.C. § 2625(k). By EPA's own definition, "reasonably available information" includes information EPA "possesses or can reasonably generate … considering [TSCA's] deadlines for prioritization *and risk evaluation*. 40 C.F.R. § 702.3 (emphasis added). Given this plain language, EPA's failure to consider what information it will need for risk evaluation during the prioritization phase violates TSCA and is arbitrary and capricious.

As a practical matter, it is important that EPA consider the information it needs for risk evaluation before beginning the prioritization process for a chemical. TSCA requires EPA to designate a chemical as low- or high-priority within twelve months of beginning the prioritization process, 15 U.S.C. § 2605(b)(1)(C). A high-

[9] In contrast, under the proposed rule EPA would have considered what information it needed for *both* prioritization and risk evaluation during the prioritization process. *See* ER 587.

priority designation triggers further statutory deadlines for completing the risk evaluation. *See id*. § 2605(b)(3)(A), (b)(4)(G).

As EPA acknowledged in the proposed Rule, these deadlines may be too short for EPA to obtain needed information if it does not start gathering information before the risk evaluation commences. ER 583 ("EPA cannot assume that it will be able to require the generation of critical information during these time frames. … Tests necessary for risk evaluation, for example, could take months or years to develop and execute."). Analyzing certain hazards—such as developmental effects, neurotoxicity, and reproductive toxicity—typically requires longer-term testing; such information is particularly crucial to evaluate risks to vulnerable subpopulations such as infants, children, and pregnant women. *See* MA 653-56; *supra* p. 32; *cf.* ER 33 (noting that EPA may "need" to require "longer-term testing … to more completely consider the hazard characteristics and exposure pathways of a chemical").

Given the intertwined deadlines for prioritization and risk evaluation, if EPA does not consider the availability of information for risk evaluation before prioritization, EPA may be unable to obtain all "reasonably available" information that Congress required it to consider within the statutory timeframes. *See* 15 U.S.C. § 2625(k). This violates TSCA.

V. Petitioners have standing

A. Petitioners have standing to bring this case on behalf of their members

Petitioners[10] have standing to challenge the Framework Rules on behalf of their members under the three-part test established in *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333, 343 (1977). First, protecting their members from exposures to toxic chemicals is central to Petitioners' purposes. *E.g.*, PA 5-6, 43-45, 77-78, 206-11, 263-66, 384-86, 394-98, 424-29. Second, neither adjudication of the legal claims at issue nor the relief requested requires individual members' participation. *See Hunt*, 432 U.S. at 342-43.

Third, Petitioners' members would have standing to sue on their own behalf: EPA's unlawful approach to prioritization and risk evaluation injures the members by increasing the risk that they will suffer harm from exposure to toxic chemicals. *See NRDC, Inc. v. U.S. EPA*, 735 F.3d 873, 878-79 (9th Cir. 2013) (finding standing where organization showed a "credible threat" that members' children would be exposed to dangerous pesticide registered by EPA); *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 948 (9th Cir. 2002) ("threat of injury" to

[10] The membership-based Petitioners are: Alaska Community Action on Toxics, Alliance of Nurses for Healthy Environments, Cape Fear River Watch, Environmental Defense Fund, Environmental Health Strategy Center, Learning Disabilities Association of America, Natural Resources Defense Council, Sierra Club, Vermont Public Interest Research Group, United Steelworkers, and WE ACT for Environmental Justice.

plaintiffs' crops from agency's planned water release schedule confers standing); *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001).

1. Threat of harm from Risk Evaluation Rule

Petitioners' members experience a credible threat of health harms from ongoing exposure to chemicals that EPA is currently evaluating pursuant to the Risk Evaluation Rule, including asbestos, 1,4-dioxane, PERC, TCE, and HBCD. There is no doubt that Petitioners' members are exposed to these chemicals. *See, e.g.*, PA 200-03, 247-48, 294-96, 332-34. United Steelworkers' members, for instance, are exposed to asbestos when they repair, maintain, or replace equipment with asbestos-containing gaskets or insulation, and through the manufacture of chlorine and caustic soda in chlor-alkali plants. PA 387-88; *see* PA 518-23, 643-45. Cape Fear River Watch has members whose drinking water comes from a river with some of the highest documented levels of 1,4-dioxane contamination in the country, contamination that is not fully removed through water treatment. PA 62, 74; *see* PA 544-47. Alaska Community Action on Toxics' members are exposed to HBCD, which bio-magnifies in the arctic animals and fish that make up integral components of their diets. PA 15-18. The serious adverse health effects of each of these chemicals, even at low levels of exposure, are well established. PA 526, 616-21, 656-57, 680-83, 859-62.

These members face a credible threat, and reasonably fear, *NRDC v. U.S.*

EPA, 735 F.3d at 878, that the flaws in EPA's Risk Evaluation Rule—e.g., exclusion of known or foreseeable exposures from risk evaluations, failure to make holistic risk determinations, deterring submission of all "reasonably available information"—will lead EPA to understate the risks posed by chemicals undergoing review. *See, e.g.*, MA 114-15 (excluding *in situ* uses of asbestos), 170 (excluding uses of 1,4-dioxane as a byproduct and impurity). If EPA understates risk, Petitioners' members will receive less protection than if the Rule complied with TSCA. *See, e.g.*, PA 18-23, 82-83, 212-15, 249, 273-76, 300-01, 329, 334, 387-91, 398-404. Although members attempt to remain vigilant to minimize their exposure, and incur costs to do so, they cannot completely avoid exposure to these chemicals. PA 39-40, 255-57, 291, 295-97, 332-33.

EPA's unlawful evaluation process thus threatens to increase the risk of members' exposure to chemicals like asbestos, HBCD, 1,4-dioxane, TCE, and PERC. These are exactly the types of risks Congress sought to reduce through TSCA, *see* 15 U.S.C. § 2601(b); *supra* pp. 6, 8, which "reinforc[es]" the conclusion that these injuries are cognizable for purposes of standing. *Baur v. Veneman*, 352 F.3d 625, 635 (2d Cir. 2003); *see also Covington v. Jefferson Cty.*, 358 F.3d 626, 638 (9th Cir. 2004).

2. Threat of harm from Prioritization Rule

Petitioners' members are also reasonably concerned about the risks to their health from exposure to lead, a chemical not yet designated as high-priority, but included in the 2014 Workplan list of chemicals from which TSCA directs EPA to select high-priority chemicals. *See* ER 371. For example, members have credible concerns about their or their children's ongoing lead exposure through drinking water, household dust, and in occupational settings. PA 39-41, 251-53, 256-58, 325-29, 390-91, 420-22.

The cumulative, irreversible damage lead wreaks on the developing brains of children is undisputed. *See In re A Cmty. Voice*, 878 F.3d 779, 787 (9th Cir. 2017); PA 440-44. Especially at low levels of exposure, each additional exposure to lead can contribute to harming children's health. *See* PA 443. Adult lead exposure is also associated with adverse health outcomes. PA 444-45.

Because the Prioritization Rule allows EPA to omit conditions of use, including known, ongoing uses of lead, from its screening review, *see supra* pp. 42, 48-49; ER 31, EPA's designation of lead as high- or low-priority will not account for the full potential risk from lead. As a result, EPA's decision about whether lead "may present an unreasonable risk," including to vulnerable subpopulations like children and workers, will not conform to statutory requirements. *See* PA 277-82, 390-91, 433-34. If lead is not designated as high-

priority, then EPA will not conduct an evaluation to determine whether lead presents an unreasonable risk that requires risk management under TSCA. Petitioners' members thus have reasonable concerns that if no risk evaluation is conducted for lead, they and their children will face an increased risk of ongoing harmful exposure.

Similarly, Petitioners' members are exposed to a variety of flame retardant chemicals, including polybrominated diphenyl ethers (PBDEs). PA 10, 80-83, 415-16. PBDEs are associated with cognitive and developmental harms in children. *See* PA 84-85, 268, 285-86. Several PBDEs are no longer produced or imported, but are still present in homes from so-called legacy uses. PA 83. Under the Prioritization Rule, EPA will ignore those uses and resulting exposures, and thus is more likely to designate these chemicals as low-priority despite PBDEs' well-recognized hazard and exposures.

3. These harms are traceable to the Framework Rules and redressable

Under the "relaxed" standards applicable here, these members' procedural injuries are traceable to the Framework Rules and will likely be redressed by a favorable decision by this Court. *See Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1083 (9th Cir. 2015). Petitioners seek to enforce a statutorily required process for evaluating chemical risks, "the disregard of which could impair" their members' "separate concrete interest" in minimizing their exposure

to harmful chemicals. *See Or. Nat. Desert Ass'n v. Dombeck*, 172 F.3d 1092, 1094 (9th Cir. 1998) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 (1992)); *see also Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1355 (9th Cir. 1994) (finding causation and redressability where agency's deficient environmental analysis might cause environmental and health consequences to be overlooked).

A favorable decision by this Court would redress this injury, because it would compel EPA to assess chemical risks comprehensively, thereby requiring EPA to accurately determine whether a chemical presents an unreasonable risk and issue protective rules to eliminate any such risk. *See Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1517-18 (9th Cir. 1992) (finding redressability where plaintiffs alleged that agency's failure to follow statutorily required procedures caused it not to recommend protecting wilderness areas, thereby opening the areas to future development); *see also N.Y. Pub. Interest Research Grp. v. Whitman*, 321 F.3d 316, 325-26 (2d Cir. 2003) (finding redressability where plaintiffs averred that Clean Air Act violations created uncertainties about whether plaintiffs were being exposed to harmful air pollution).

B. Petitioners have organizational and informational standing to challenge the Risk Evaluation Rule

Petitioners Environmental Working Group, Union of Concerned Scientists, Safer Chemicals Healthy Families, and Asbestos Disease Awareness Organization

have standing because the organizations have suffered "both a diversion of [their] resources and frustration of [their] mission[s]." *Fair Housing Council of San Fernando Valley v. Roommate.com, LLC*, 666 F.3d 1216, 1219 (9th Cir. 2012) (internal quotation marks omitted). These organizations' missions will be frustrated by the Risk Evaluation Rule insofar as a core part of their work is providing their constituencies with accurate information about chemicals to which they are exposed. PA 52-54, 60, 229-31, 307; *see also* PA 364-65 (explaining that mission includes ensuring member-scientists have access to data). In this work, the groups and their members rely extensively on government information about the uses and health risks of chemicals, including information TSCA requires EPA to release. PA 59-60, 225, 344-47; 15 U.S.C. § 2605(b)(4)(C) (requiring EPA to "publish" final risk evaluations). TSCA aims to develop "adequate information" about the effects of chemicals on health and the environment, 15 U.S.C. § 2601(b)(1), and to "increase access" to that information, H.R. Rep. No. 114-176, at 16.

Because the Risk Evaluation Rule unlawfully allows EPA to exclude conditions of use and ignore the combined exposure from multiple uses of a chemical, the information it publishes concerning a chemical's "hazards and exposures" will be incomplete. *See* 15 U.S.C. § 2605(b)(4)(F)(i). This will frustrate these Petitioners' missions of creating and distributing accurate,

comprehensive educational materials about chemical risks.

Instead of relying on EPA, the groups and their members will be forced to "expend additional resources that they would not otherwise have expended" on new research and data collection to close gaps in the government's data. *See* PA 230-31, 345-47. These injuries give rise to organizational standing. *See Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1040 (9th Cir. 2015); *Am. Canoe Ass'n v. City of Louisa Water & Sewer Comm'n,* 389 F.3d 536, 544-47 (6th Cir. 2004); *Fair Housing Council*, 666 F.3d at 1219.

In addition, the Risk Evaluation Rule will prevent Petitioners and their members from "obtain[ing] information which must be publicly disclosed pursuant to the statute." *See Fed. Election Comm'n v. Akins*, 524 U.S. 11, 20-21 (1998); PA 21, 59-60, 75, 223-28, 281-82, 343-47, 385, 400-01. This informational injury also gives rise to standing. *See Friends of Animals v. Jewell*, 824 F.3d 1033, 1041 (D.C. Cir. 2016).

CONCLUSION

Petitioners respectfully request that this Court grant the petitions for review and set aside these rules "in part." 15 U.S.C. § 2618(c)(2). Vacatur, along with remand, is the presumptively appropriate remedy here. *See Cal. Wilderness Coal. v. U.S. Dep't of Energy*, 631 F.3d 1072, 1095 (9th Cir. 2011). Petitioners request that the Court vacate and remand the following provisions of the Framework

Rules: 40 C.F.R. §§ 702.5(b), (e), 702.7(a), 702.9(b)-(c), (f), 702.31(d), 702.37, 702.41(a)(5), (a)(7)-(9), (b)(2), (c)(1), (c)(4)(i), (c)(4)(iii), (d)(2), 702.43(a)(1), 702.47, 702.49(b)(1), (c), (d), and the following portions of the preambles: Prioritization, IV.B (ER 31), IV.J (ER 34-34), and Risk Evaluation, III.B (ER 3-6), III.G (ER 10-13), III.H.1.d-e (ER 14-15), III.H.2 (ER 15-16), III.I.1 (ER 16), and III.I.6 (ER 19). Petitioners also respectfully request that the Court issue declaratory relief that TSCA requires priority designations and risk evaluations to consider all circumstances within the statutory definition of conditions of use.

April 16, 2018

Respectfully submitted,

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STATEMENT OF RELATED CASES

Petitioners are unaware of any related cases within the definition of Circuit Rule 28-2.6.

Dated: April 16, 2018

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 15,332 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2016 and 14-point Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on April 16, 2018.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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